Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1011556	01/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ivf Laboratory Of Central Florida Llc	5971 Brick Court Suite 1001, Winter Park, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA initial survey was conducted at IVF Laboratory of Central Florida from January 17-21, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of quality control (QC) logs and interview, the laboratory failed to document the corrective action taken when the PreciControl Universal controls were out of range on the Roche Cobas e411 chemistry analyzer from 07/01/2024 to 01/17/2025. Findings: Review of the Individual QC Chart showed level one and two controls for Luteinizing Hormone (LH) were run on 08/02/2024 two times each. Review of the Individual QC Chart showed level one control for LH was run on 08/05/2024 three times. Review of the Individual QC Chart showed level two control for LH was run on 08/05/2024 two times. Review of the Individual QC Chart showed level one and two controls for Progesterone were run on 08/15/2024 seven times each. Review of the Individual QC Chart, the Daily QC printouts, and the Out of Range Log failed to include documentation of what corrective actions were taken for the QC that was out of range. Review of the Individual QC Chart showed level one control for LH

	was run on 08/19/2024 once. Review of the Individual QC Chart, the Daily QC Printouts, and the Out of Range Log failed to include documentation what corrective action was taken for the QC that was out of range and if any patient samples were tested that day. On 01/17/2025 at 1:10 PM, the Laboratory Director acknowledged the corrective action taken when the QC was out of range was not always documented.